

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Jeffrey L. CLELAND et al.

Application No.: 10/080,502

Filing Date: February 22, 2002

For: ERODIBLE POLYMERS FOR  
INJECTION

Examiner: C. Azpuru

Group Art Unit: 1615

Confirmation No.: 8669

**APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 CFR 1.705**

MS Issue Fee  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Applicants respectfully request reconsideration of the patent term adjustment indicated in the Notice of Allowance. This application for patent term adjustment is being filed with payment of the issue fee and is, therefore, timely. The fee required under 37 CFR 1.705(b)(1) as set forth in 37 CFR 1.18(e) is enclosed with the present application.

**Summary**

*Part A* (35 § U.S.C. 154(b)(A) ("A" delay)). Applicants respectfully provide facts addressing Part A recalculation. In sum, Applicants calculate that the Office delayed a total of 641 days. Applicants' delay was 526 days, leading to 115 days of adjustment of patent term.

*Part B* (35 § U.S.C. 154(b)(B) (“B” delay)). For completeness, Applicants also respectfully provide facts addressing Part B calculation. Applicants understand and appreciate that the Office does not currently calculate Part B term until issuance and that this portion of the request will likely be dismissed as premature at this point. In sum, Applicants calculate 338 days of B type delay (time from February 22, 2005, which is three years from the filing date, to January 26, 2006, when a Request for Continued Exam (RCE) was filed).

Taking Part A and Part B into account as a total, Applicants respectfully request a credit of 899 days be added to the 80 days of adjustment as indicated on the Notice of Allowance. The additional credit, minus Applicants’ delay (526 days), results in a revised total of 453 days of patent term adjustment.

According to the Office’s Initial Determination of Patent Term Adjustment received with the Notice of Allowance, mailed May 3, 2010, Applicants are entitled to 80 days adjustment of patent term. Applicants respectfully disagree with the Office’s calculation of Patent Term Adjustment of 80 days. Reconsideration is respectfully requested in view of the following facts and applicable rules.

#### Statement of Facts

##### ***Part A***

The Office mailed a Notice to File Missing Parts on March 20, 2002. Applicants mailed a Response to the Notice of Missing Parts on May 20, 2002. Applicants calculate 0 days of Applicants’ delay in accordance with 35 USC 154(b)(2)(C)(ii) and 37 CFR 1.704(b).

The Office mailed a Non-Final Office Action on March 25, 2004. The Non-Final Office Action mailed was not within 14 months of the filing date of the present application. Applicants calculate 338 days of USPTO delay in accordance with 35 USC 154(b)(1)(A)(i) and 37 CFR 1.702(a)(1), 1.703(a)(1).

Applicants filed a Response to the March 25, 2004 Non-Final Office Action on September 27, 2004. Applicants calculate 94 days of Applicants' delay in accordance with 35 USC 154(b)(2)(C)(ii) and 37 CFR 1.704(b).

The Office mailed a Final Office Action on July 26, 2005. Applicants calculate 180 days of USPTO delay in accordance with 35 USC 154(b)(1)(A)(ii) and 37 CFR 1.703(a)(2).

Applicants filed a Request for Continued Exam and Response to the July 26, 2005 Final Office Action on January 26, 2006. Applicants calculate 92 days of Applicants' delay in accordance with 35 USC 154(b)(2)(C)(ii) and 37 CFR 1.704(b).

The Office mailed a Non-Final Office Action on May 4, 2006. Applicants calculate 0 days of USPTO delay in accordance with 35 USC 154(b)(1)(A)(ii) and 37 CFR 1.703(a)(3).

Applicants filed a Response to the May 4, 2006 Non-Final Office Action on November 6, 2006. Applicants calculate 94 days of Applicants' delay in accordance with 35 USC 154(b)(2)(C)(ii) and 37 CFR 1.704(b).

The Office mailed a Final Office Action on March 29, 2007. Applicants calculate 23 days of USPTO delay in accordance with 35 USC 154(b)(1)(A)(ii) and 37 CFR 1.703(a)(2).

Applicants filed a Notice of Appeal and Response to the March 29, 2007 Final Office Action on September 28, 2007. Applicants calculate 91 days of Applicants' delay in accordance with 35 USC 154(b)(2)(C)(ii) and 37 CFR 1.704(b).

The Office mailed an Advisory Action on October 9, 2007. Applicants calculate 0 days of USPTO delay in accordance with 35 USC 154(b)(1)(A)(ii) and 37 CFR 1.703(a)(3).

Applicants filed a Request for Continued Exam and Supplemental Amendment in Response to the October 9, 2007 Advisory Action on October 31, 2007. Applicants calculate 0 days of Applicants' delay in accordance with 35 USC 154(b)(2)(C)(ii) and 37 CFR 1.704(b).

The Office mailed a Non-Final Office Action on February 7, 2008. Applicants calculate 0 days of USPTO delay in accordance with 35 USC 154(b)(1)(A)(ii) and 37 CFR 1.703(a)(3).

Applicants filed a Response to the February 7, 2008 Non-Final Office Action on April 8, 2008. Applicants calculate 0 days of Applicants' delay in accordance with 35 USC 154(b)(2)(C)(ii) and 37 CFR 1.704(b).

The Office mailed a Non-Final Office Action on July 9, 2008. Applicants calculate 0 days of USPTO delay in accordance with 35 USC 154(b)(1)(A)(ii) and 37 CFR 1.703(a)(2).

Applicants filed a Response to the July 9, 2008 Non-Final Office Action on January 9, 2009. Applicants calculate 92 days of Applicants' delay in accordance with 35 USC 154(b)(2)(C)(ii) and 37 CFR 1.704(b).

The Office mailed a Final Office Action on March 23, 2009. Applicants calculate 0 days of USPTO delay in accordance with 35 USC 154(b)(1)(A)(ii) and 37 CFR 1.703(a)(2).

Applicants filed a Response to the March 23, 2009 Final Office Action on August 25, 2009. Applicants calculate 63 days of Applicants' delay in accordance with 35 USC 154(b)(2)(C)(ii) and 37 CFR 1.704(b).

The Office mailed an Advisory Action on September 21, 2009. Applicants calculate 0 days of USPTO delay in accordance with 35 USC 154(b)(1)(A)(ii) and 37 CFR 1.703(a)(2).

Applicants filed a Request for Continued Exam in response to the September 21, 2009 Advisory Action on September 23, 2009. Applicants calculate 0 days of Applicants' delay in accordance with 35 USC 154(b)(2)(C)(ii) and 37 CFR 1.704(b).

The Office mailed a Final Office Action on December 9, 2009. The Final Office Action was supplanted (replaced) by a Notice of Allowance mailed by the Office on May 3, 2010. In the Examiner Interview Summary mailed May 3, 2010, the Examiner stated "Ms. Shortle called because the prior final action did not reflect the claims as amended in Sept. 2009, nor did it address any of applicant's comments. This amendment was overlooked once the RCE was filed, and a first

action final was erroneously mailed. A further search was conducted and no other prior art could be found. The application appears to be in condition for allowance.” The Notice of Allowance mailed May 3, 2010 is responsive to the Request for Continued Exam filed September 23, 2009, therefore, Applicants calculate 100 days of USPTO delay in accordance with 35 USC 154(b)(1)(A)(ii) and 37 CFR 1.703(a)(3).

In sum, the Office delayed a total of 641 days. Applicants’ delay was 526 days. Thus, based on these calculations, for this aspect of patent term adjustment, the patent term adjustment is 115 days.

### ***Part B***

The Office mailed a Notice of Allowance on May 3, 2010. The Office has failed to issue a patent within 3 years after the date on which the present application was filed (February 22, 2002), and a Request for Continued Examination (RCE) was filed on January 26, 2006. Based on these facts, Applicants respectfully submit that they are entitled to an additional credit of 338 days in accordance with 35 USC 154(b)(1)(B) and 37 CFR 1.702(b), 1.703(b).

Applicants respectfully request reconsideration of the adjustment indicated on the Notice of Allowance, in view of the decision in *Wyeth v. Kappos*, No. 2009-1120 (Fed. Cir. January 7, 2010). Applicants are entitled to adjustment of patent term for all non-overlapping days of PTO delay under both 35 § U.S.C. 154(b)(A) (“A” delay) and 35 § U.S.C. 154(b)(B) (“B” delay). Under *Wyeth*, “B” delay begins three years after filing; it does not overlap with “A” delay other than days falling on the same calendar date.

In the present application, the Office has failed to issue a patent within 3 years of the filing date (February 22, 2002). Under *Wyeth*, Applicants are entitled to additional adjustment for days of “B” delay—days after February 22, 2005 (not including time consumed by continued examination, or any overlap with the USPTO’s failure to issue an Office Action within 14 months) until issuance. Accordingly, Applicants calculate 338 days of “B” delay (time from February 22, 2005 until the filing of a Request for Continued Exam on January 26, 2006).

Applicants request recalculation of the adjustment in view of *Wyeth*, which requires adjustment for both “A” and “B” delays. As no detailed calculation was given regarding “B” delay in the Notice of Allowance, Applicants respectfully request that the Office correctly calculate the adjustment in accordance with *Wyeth*.

In sum, Applicants’ independent calculation yielded Part A delay by the Office (+641 days) added to Part B delay by the Office (+338 days) totals 979 days. Applicants’ independent calculation yielded a total USPTO delay of 979 days and Applicants’ delay of 526 days, for a revised total of 453 days of additional patent term. Based on the foregoing information, Applicants respectfully request reconsideration of the patent term adjustment and an adjustment of an additional 453 days (115 days under Part A and 338 days under Part B).

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing Attorney Docket No. 146392000500.

Dated: June 9, 2010

Respectfully submitted,

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